

24

IMPACT OF SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS ON
MEDICAL PRACTICE IN INDUSTRY

CERTAIN-TEED CORPORATION OCCUPATIONAL MEDICINE SEMINAR
VALLEY FORGE, PA
JUNE 16-17, 1977:
MORTON CORN, PH.D.

PLAINTIFF'S EXHIBIT

ASA-843

INTRODUCTION

IT IS AN HONOR TO BE INVITED TO ADDRESS THIS GROUP. IT WAS
MY PRIVILEGE TO ACCEPT THE INVITATION AND MY PLEASURE TO BE WITH
YOU TODAY.

MR. KITTLESTADT INFORMED ME THAT THE MAJORITY OF THOSE IN
THE AUDIENCE ARE PART-TIME EMPLOYEES OF THE CERTAIN-TEED CORPOR-
ATION, PHYSICIANS WHO PROVIDE SERVICE TO CERTAIN-TEED. IT IS THE
PURPOSE OF MY PRESENTATION TODAY TO CALL ATTENTION TO THE EVOLV-
ING CONCEPTS OF FEDERAL REGULATION OF SAFETY, HEALTH AND ENVIRON-
MENT IN THE U.S. AND THEIR IMPLICATIONS FOR PROFESSIONALS WITH
RESPONSIBILITY IN THESE AREAS. THERE ARE EXTENSIVE PROFESSIONAL
RAMIFICATIONS OF THESE CHANGING PHILOSOPHIES TO THE INDIVIDUAL
PRACTITIONER. IT IS EVEN MORE DIFFICULT TO TRANSLATE THESE IM-
PACTS TO THE ROLE OF THOSE FULFILLING A PART-TIME MEDICAL RESPON-
SIBILITY, THAN IT IS TO RELATE THEM TO THOSE SERVING AS FULL-TIME

CORPORATE OCCUPATIONAL PHYSICIANS. IN FACT, IT WILL BE YOUR RESPONSIBILITY TO SUPERIMPOSE ON MY PRESENTATION THE ADAPTATION OF THE PART-TIME PHYSICIAN TO THE RESPONSIBILITIES AND NEEDS DESCRIBED.

FIRST, WE SHOULD RECOGNIZE THAT MUCH OF WHAT WILL BE DISCUSSED IS CONTROVERSIAL. THIS IS A PERIOD OF TRANSITION, IN THE SENSE OF CHANGES FROM THAT WHICH EXISTED PRIOR TO THE LATE 1960'S IN THE FIELDS OF OCCUPATIONAL SAFETY AND HEALTH AND THE ENVIRONMENT. ALSO, IT IS A TRANSITION IN THE MORE IMMEDIATE SENSE OF THE NEW ADMINISTRATION IN WASHINGTON. IT IS ALREADY IN THE PROCESS OF ALTERING SOME OF THE PROCEDURES AND APPROACHES THAT WERE FORMULATED DURING THE PREVIOUS ADMINISTRATION.

IN 1959 THERE WERE VERY FEW REGULATIONS AFFECTING THE CHEMICAL INDUSTRY AND THE ENVIRONMENT, EITHER THE ENVIRONMENT OUTSIDE OR INSIDE THE WORKING FACILITY. SOME OF THE ACTS, LAWS AND REGULATIONS WHICH HAVE SINCE COME INTO EFFECT ARE AS FOLLOWS:

THE CLEAN AIR ACT; THE CLEAN WATER ACT; THE OCCUPATIONAL SAFETY AND HEALTH ACT; THE MINE SAFETY AND HEALTH ACT; THE COASTAL ZONE

MANAGEMENT ACT; THE ENDANGERED SPECIES ACT; THE ENERGY SUPPLY AND ENVIRONMENTAL COORDINATION ACT; THE FEDERAL ENVIRONMENTAL PESTICIDE CONTROL ACT; THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT; THE FISH AND WILDLIFE COORDINATION ACT; THE HAZARDOUS MATERIALS TRANSPORTATION ACT; THE MARINE PROTECTION RESEARCH AND SANCTUARY ACT; THE RESOURCES CONSERVATION AND RECOVERY ACT; THE SOLID WASTE DISPOSAL ACT; THE NEW TOXIC SUBSTANCES CONTROL ACT; THE TRANSPORTATION SAFETY ACT; AND THE CONSUMER PRODUCT SAFETY ACT. VIRTUALLY ALL OF THESE STATUTES DEEPLY INVOLVE THE SCIENTIFIC, TECHNICAL AND BUSINESS COMMUNITIES AND YET THESE GROUPS HAVE ONLY OF LATE BECOME AWARE OF THE RELEVANCE OF THIS LEGISLATION TO THEIR EVERYDAY LIFE, AND TO THEM IN THEIR ROLES AS PRACTICING PROFESSIONALS AND BUSINESSMEN. THERE IS LITTLE DOUBT THAT IN RETROSPECT THE PAST 10 TO 15 YEARS WILL BE CHARACTERIZED BY MANY AS A PERIOD OF MAJOR FEDERAL INITIATIVES TO REGULATE TECHNOLOGICAL AND SCIENTIFIC ASPECTS OF OUR COMPLEX SOCIETY. A RECENT ISSUE OF BUSINESS WEEK DEVOTES ITS MAJOR STORY TO THIS SUBJECT, WHICH IT CALLS "GOVERNMENT INTERVENTION". ALMOST ALL OF THE AFOREMENTIONED STATUTES ARE DEVOTED TO REGULATING THE CHEMICAL ENVIRONMENT.

4

TO FURTHER STRESS THE EXTENT OF GOVERNMENT INVOLVEMENT, LET US BRIEFLY LOOK AT THE STAFFING OF SELECTED FEDERAL REGULATORY AGENCIES. THE ENVIRONMENTAL PROTECTION AGENCY NOW EMPLOYS APPROXIMATELY 10,000; THE PROPOSED EPA BUDGET OFFERED BY THE CARTER ADMINISTRATION ADDS OVER 600 POSITIONS, 182 OF WHICH WILL BE ALLOCATED TO ADMINISTERING THE NEW TOXIC SUBSTANCES CONTROL ACT. IN FACT, AT THE RECENT APPROPRIATIONS HEARINGS FOR EPA, MR. JOHN QUARLES, ACTING ADMINISTRATOR OF THE AGENCY, INFORMED THE COMMITTEE THAT BY 1980 THE ADMINISTRATION OF THE TOXIC SUBSTANCES CONTROL ACT WOULD REQUIRE AN AGENCY ABOUT THE SIZE OF THE FOOD AND DRUG ADMINISTRATION, THAT IS, ABOUT 7,000 PERSONS AND A \$250 x 10⁶ ANNUAL BUDGET.

THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION EMPLOYS APPROXIMATELY 2,700; THE MINE ENFORCEMENT AND SAFETY ADMINISTRATION EMPLOYS APPROXIMATELY 2,400; THE FOOD AND DRUG ADMINISTRATION EMPLOYS ABOUT 7,000. THE CONSUMER PRODUCT SAFETY COMMISSION: 900. THESE ARE SUBSTANTIAL NUMBERS OF FEDERALLY EMPLOYED REGULATORS. ALL TOLD, I BELIEVE THERE ARE SOMEWHERE IN THE NEIGHBORHOOD OF 85,000 FEDERAL EMPLOYEES PERFORMING REGULATORY FUNCTIONS WHICH

COULD AFFECT THE PROFESSIONAL SCIENTIFIC AND TECHNICAL COMMUNITY. THE EMPLOYMENT FIGURES FOR THE STATE AND LOCAL GOVERNMENTS EMPLOYING ADDITIONAL INDIVIDUALS FOR DUTIES RELATED TO THE SAME STATUTES, AND MONITORED BY THE FEDERAL GOVERNMENT IN THEIR ACTIVITIES, ARE HARDER TO COME BY AND I CANNOT OFFER THEM HERE.

THERE CAN BE ENORMOUS AND DRAMATIC REPERCUSSIONS OF REGULATORY ACTION IN THE AREA OF SCIENTIFIC DECISION MAKING. THE MOST RECENT EXAMPLES OF THIS ARE THE FOOD AND DRUG ADMINISTRATION BAN ON SACHARIN, CALLED FOR BY THE DELANEY CLAUSE IN THE PURE FOOD AND DRUG AND COSMETICS ACT OF 1958, AND THE FEDERAL COURT DECISION TO HALT CONSTRUCTION OF THE TELlico DAM IN THE TENNESSEE VALLEY AUTHORITY ELECTRICITY GENERATING GRID, ON THE BASIS OF THE PROVISIONS OF THE ENDANGERED SPECIES ACT OF 1973.

IT IS NOT MY PURPOSE TO ARGUE THE MERITS OF EITHER OF THESE CASES HERE. SUFFICE IT TO SAY THAT THE PUBLIC IS THOROUGHLY CONFUSED WITH RESPECT TO THE MERITS OF BOTH DECISIONS. FURTHERMORE, IN BOTH CASES, THERE ARE VALID SCIENTIFIC ARGUMENTS WHICH COULD SUPPORT OR REFUTE THE DECISIONS REACHED. IN OTHER WORDS, DECISIONS SUCH AS THESE TWO ARE, INDEED, ON THE FOREFRONT OF OUR KNOWLEDGE

OF THE PARTICULAR SUBJECTS INVOLVED, AND REQUIRE EXTRAPOLATION FROM THE AVAILABLE DATA BASE, WITH ALL THE INDIVIDUAL SUBJECTIVE DISTORTIONS INHERENT IN SUCH EXTRAPOLATION. IN THE CASE OF THE DELANEY CLAUSE, THE FLEXIBILITY OF THE REGULATOR IS NON-EXISTENT; THE STATUTE INCORPORATES THE EXTRAPOLATION OF EFFECTS TO MAN ON THE BASIS OF A ZERO EXPOSURE THRESHOLD FOR CARCINOGEN RESPONSE BY ANIMALS.

HOW SHOULD MEMBERS OF THE MEDICAL, SCIENTIFIC, TECHNICAL AND BUSINESS COMMUNITIES RELATE TO THESE LEGISLATIVE PRODUCTS? WHAT OPTIONS ARE AVAILABLE? WHAT HAS BEEN OUR ROLES TO DATE? FIRST, LET US EXAMINE THE NATURE OF THE REGULATORY ENABLING LEGISLATION AND THEN PROCEED TO THESE QUESTIONS.

MOST STATUTES HAVE BOTH GENERAL AND SPECIFIC PROVISIONS. THE SPECIFIC PROVISIONS OF THE ACT LEAVE LITTLE FLEXIBILITY FOR THE ADMINISTRATOR. AGAIN, THE DELANEY CLAUSE IS AN EXAMPLE OF SPECIFICITY. THE NUMEROUS CONSENSUS SAFETY STANDARDS ADOPTED BY OSHA ARE ILLUSTRATIVE OF VERY SPECIFIC REGULATIONS. THERE ARE NUMEROUS OTHER EXAMPLES IN THE ACTS MENTIONED EARLIER. HOWEVER, IT IS MORE

COMMON FOR THE STATUTE TO LAY OUT A BROAD DIRECTION FOR THE ADMINISTRATION OF THE ACT AND TO CHARGE THOSE, WHO THROUGH APPOINTIVE OR CIVIL SERVICE QUALIFICATIONS ARE ENTRUSTED TO ENFORCE THE STATUTE, TO CONSTRUCT DETAILED ADMINISTRATIVE DIRECTIVES FOR THE REGULATORY FORCE IN THE FIELD. EXAMPLES OF THIS APPROACH ARE THE RULES FOR STATIONARY SOURCE EMISSIONS TO THE ATMOSPHERE, WHICH THE EPA ISSUES UNDER THE AUTHORITY OF THE CLEAN AIR ACT. EPA SPECIFIES THE STANDARDS THAT WILL BE MET, THE MANNER OF TESTING THE STATIONARY SOURCE, AND THE REPORTING SCHEME FOR RESULTS OF SUCH TESTING. IN THE CASE OF THE OCCUPATIONAL SAFETY AND HEALTH ACT, THE STATUTE STATES THAT STANDARDS MUST BE ADOPTED FOR THE WORKPLACE. A PROCEDURE IS PRESENTED FOR ARRIVING AT SUCH STANDARDS. THUS, THE AGENCY CAN FORM AN ADVISORY COMMITTEE TO GATHER INFORMATION IN PUBLIC HEARINGS. ONCE A PROPOSAL IS FRAMED BY THE AGENCY, WITH OR WITHOUT THE AID OF AN ADVISORY COMMITTEE, THERE MUST BE A PUBLIC HEARING. A PUBLIC COMMENTARY PERIOD FOLLOWING THE PUBLIC HEARING IS REQUIRED. WITHIN A SPECIFIED PERIOD OF TIME THE AGENCY MUST THEN PROMULGATE A FINAL STANDARD. THE EFFECTIVE DATE OF THE STANDARD

IS SPECIFIED, USUALLY 90 OR 180 DAYS FOLLOWING THE PROMULGATION. WITH THIS PROCEDURE, THE CONSTRAINTS OF THE AGENCY ARE THAT THE STANDARD PROMULGATED MUST REFLECT THE PUBLIC RECORD GATHERED BOTH DURING THE HEARING PROCESS AND THROUGH WRITTEN COMMENTARY TO THE AGENCY. FOR THOSE UNHAPPY WITH THE REGULATORY STANDARDS PROMULGATED IN THIS MANNER, RECOURSE CAN BE MADE TO THE OCCUPATIONAL SAFETY AND HEALTH COMMISSION, WHICH WAS ESTABLISHED BY THE OCCUPATIONAL SAFETY AND HEALTH ACT. THE COMMISSION IS COMPOSED OF THREE INDIVIDUALS WHO RULE ON THE MERITS OF EACH CONTEST. IF THE DECISION OF THE COMMISSION IS NOT SATISFACTORY TO THE REGULATEE, THEN THE CHALLENGE TO THE AGENCY AND THE REGULATORY COMMISSION DECISION CAN BE ESCALATED TO THE FEDERAL COURT OF APPEALS AND, IF NECESSARY, TO THE SUPREME COURT. THIS COURSE OF EVENTS DOES OCCUR. FOR EXAMPLE, THE RIGHT OF ENTRY TO THE EMPLOYER PREMISES BY OSHA INSPECTORS IS BEING CHALLENGED UNDER THE BILL OF RIGHTS RIGHT TO PRIVACY AND NECESSITY FOR A SEARCH WARRANT. THIS CHALLENGE IS NOW BEFORE THE SUPREME COURT. IN OTHER STATUTES, THE DIRECT ROUTE TO THE COURT OF APPEALS IS MORE COMMON. A RESULT OF THE CHALLENGE TO

THE REGULATORY AGENCY IS USUALLY A STAY OF THE REGULATION UNTIL SUCH TIME AS THE COURT RULES ON THE MERITS OF THE CASE.

WITHIN THIS FRAMEWORK OF ADMINISTRATIVE PROCEDURES, WHERE CAN THE MEMBERS OF THE SCIENTIFIC, MEDICAL AND BUSINESS COMMUNITIES CONTRIBUTE OR, IF NECESSARY, INTRUDE? THE VERY FIRST STAGE OF INVOLVEMENT IS AT THE ADVISORY LEVEL. THE ENVIRONMENTAL PROTECTION AGENCY HAS A SCIENCE ADVISORY BOARD WHICH REFERS TO THE ADMINISTRATOR MATTERS OF SCIENTIFIC CONCERN. THE ADMINISTRATOR MAY ALSO REFER TO THE BOARD MATTERS FOR INVESTIGATION. MANY OF THE AGENCIES PERFORM THEIR OWN RESEARCH. EPA HAS A VERY EXTENSIVE RESEARCH PROGRAM, BUDGETED IN THE NEIGHBORHOOD OF \$60-70 MILLION A YEAR. THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION IS SERVICED BY THE NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH FOR ITS RESEARCH; THE MINE ENFORCEMENT SAFETY AGENCY IS SERVICED IN ITS RESEARCH BY THE BUREAU OF MINES. CERTAIN AGENCIES CONDUCT THEIR OWN RESEARCH, SUCH AS FDA. IN GENERAL, THE NATIONAL INSTITUTES OF HEALTH SERVICE A WIDE VARIETY OF AGENCIES. MUCH OF THE RESEARCH IS PERFORMED THROUGH CONTRACTURAL MECHANISMS WITH QUALIFIED INVESTIGATORS OUTSIDE OF GOVERNMENT. THE OPPORTUNITY FOR THE INTRODUCTION

OF DATA INTO THE DIALOGUE IS MAINLY THROUGH THE MECHANISM OF RESEARCH, BUT IN THE REGULATORY AREAS THAT WE ARE DISCUSSING HERE THE RESEARCH HAS NOTORIOUSLY LAGGED THE MONITORIAL NEEDS FOR DATA.

AN ILLUSTRATION OF THE INADEQUACY OF CURRENT KNOWLEDGE RELATES TO THE MORE THAN 10,000 PAGES OF PUBLIC RECORD ACCUMULATED PRIOR TO PROMULGATION BY OSHA OF A STANDARD FOR WORKPLACE EXPOSURE TO COKE OVEN EMISSIONS. THE AVAILABLE DATA PROVIDED AN INADEQUATE DOSE-RESPONSE CURVE FOR COKE OVEN EMISSIONS; BY DOSE-RESPONSE CURVE I MEAN WHAT QUANTITY OF EMISSIONS INHALED FOR WHAT PERIOD OF TIME WOULD CAUSE WHAT INCIDENCE OF LUNG CANCER IN THOSE EXPOSED? FURTHERMORE, THE SPECIFIC AGENT CAUSING THE CANCER WAS UNKNOWN; A SURROGATE MEASURE OF THE ACTIVE AGENT WAS SELECTED AS THAT WHICH HAD TO BE MONITORED TO BE SURE THAT COKE OVEN EMISSIONS WERE NOT EXCESSIVE. THE OTHER ASPECT OF THE COKE OVEN STANDARD THAT REQUIRED SCIENTIFIC AND TECHNOLOGICAL INPUT WAS THE SPECIFICATION OF ENGINEERING CONTROLS FOR COKE OVENS. THE AGENCY INCLUDED IN THE STANDARD VERY SPECIFIC CONTROLS WHICH WOULD HAVE TO BE INSTALLED BY CERTAIN FUTURE DATES. ALL OF THESE ABOVE MATTERS DREW

EXTENSIVE COMMENT FROM THE PUBLIC AND FROM THE SCIENTIFIC AND ENGINEERING COMMUNITIES. THE FINAL STANDARD WAS PROMULGATED AND OCCUPIED APPROXIMATELY THREE TO FOUR PAGES IN THE FEDERAL REGISTER, BUT ABOUT FORTY PAGES WERE DEVOTED TO EXPLAINING, ON THE BASIS OF THE PUBLIC RECORD, THE REASONS FOR INCLUSION OF ITEMS IN THE ADOPTED STANDARD ON THE BASIS OF LESS-THAN-COMPLETE DATA.

IN MANY CASES, THE OSHA PROCEDURES ARE NOT FOLLOWED BY REGULATORY AGENCIES. IN MANY REGULATIONS THERE IS NO PROVISION FOR PUBLIC HEARING OR OTHER ADMINISTRATIVE PROCEDURES THAT WOULD BRING RULEMAKING INTO THE PUBLIC DOMAIN. IN THESE CASES, WHEN A RULE APPEARS IN THE FEDERAL REGISTER, IT IS A FINAL REGULATION ADOPTED BY THE AGENCY. ACCORDING TO BUSINESS WEEK, ABOUT 72,000 FEDERAL REGISTER PAGES OF REGULATIONS APPEARED IN 1975, INCREASED FROM 54,000 IN 1970. THE SUBMISSION OF DATA AND ARGUMENTS BY THE SCIENTIFIC COMMUNITY AND OTHERS HAS, HOPEFULLY, OCCURRED DURING THE PERIOD PRECEDING ADOPTION OF THE REGULATION, AT LEAST BY CONSULTANTS AND ADVISORY COMMITTEES. ALL ADVISORY COMMITTEE MEETINGS ARE NOW OPEN TO THE PUBLIC AND THERE ARE, CERTAINLY IN THE CASE OF ENVIRONMENTAL REGULATIONS, PUBLIC INTEREST GROUPS PRESENT.

THE SEPARATION OF FACT FROM OPINION IN THE OFFERING OF ADVICE IS CRUCIAL. IT WAS MY EXPERIENCE THAT SOME VERY REPUTABLE CONSULTANTS WOULD OFTEN CONFUSE THESE TWO MATTERS AND NOT DOCUMENT THEIR OPINIONS. OFTEN, THE CREDENTIALS OF SUCH INDIVIDUALS ARE VERY IMPRESSIVE. THE INFORMED PUBLIC AND EVEN THE REASONABLY WELL INFORMED AGENCY MEMBERS ARE CONFUSED BY THEIR TESTIMONY OR THE INTENT OF THE TESTIMONY, WHEN FACT AND OPINION ARE NOT SEPARATED OR APPROPRIATELY REFERENCED.

ANOTHER FACET OF THE PRESENTATION OF SCIENTIFIC TESTIMONY AS PART OF THE REGULATORY PROCESS IN THE UNITED STATES IS THAT THE SAME PERSONS TEND TO ACT IN THE PROCEEDINGS. THERE IS A SMALL CADRE OF THE SCIENTIFIC COMMUNITY WHO ARE DEEPLY INVOLVED IN PUBLIC POLICY AND THEIR NAMES TEND TO APPEAR OVER AND OVER AGAIN. THE VAST MAJORITY OF THE SCIENTIFIC AND TECHNICAL COMMUNITY ARE NOT INVOLVED. THIS IS UNFORTUNATE. IT APPEARS TO ME THAT FACTS WILL OUT BY ONE MEANS OR ANOTHER. WE HAVE ALL OBSERVED TOO MANY CASES WHERE RELUCTANT OR LATE DIVULGEMENT HAS LEAD TO MORE PROBLEMS FOR PRIVATE SECTOR COMPANIES THAN THE INFORMATION ITSELF.

THE PUBLIC IS VERY SENSITIVE TO THE GOOD CITIZEN ROLE OF PRIVATE CORPORATIONS. SECRECY OF INVOLVEMENTS AND DATA CAN, I BELIEVE, ONLY HARM THE IMAGE AND THE REALITY OF CORPORATIONS AND THEIR BEHAVIOR.

IT IS APPROPRIATE THAT WE ALSO NOTE THE ROLE OF THE LEGAL PROFESSION VIS-A-VIS THE SCIENTIFIC COMMUNITY IN REGULATORY ACTIONS. THE INTRODUCTION OF SO MANY STATUTES BRINGS THE LEGAL PROFESSION VERY MUCH INTO THE PICTURE. EARLIER WE NOTED THAT THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION NOW EMPLOYS APPROXIMATELY 2,700 PERSONS; APPROXIMATELY 250 OF THESE ARE LAWYERS. OF THE ONE HUNDRED THOUSAND CITATIONS FOR VIOLATIONS OF STANDARDS ISSUED BY THAT AGENCY DURING 1975 IN ITS REGULATORY FUNCTIONS, SOME SIX THOUSAND WERE CONTESTED. LAWYERS ARE VERY INVOLVED IN RESOLUTION OF SCIENTIFIC AND TECHNICAL ISSUES. AS AN EXAMPLE, A MAJOR CASE IN OSHA LEGAL HISTORY WAS THE RELEVANCE OF AIR AND BIOLOGICAL SAMPLING TO THE ESTABLISHMENT OF BODY BURDENS OF LEAD. THE PROCEEDINGS OF THAT CONTEST OF CITATION READS LIKE A TOXICOLOGY-PHYSIOLOGY TEXTBOOK. THE COMPLEXITY OF MANY

CASES PLACES EXTREME BURDENS ON THE LEGAL COMMUNITY, AND AN ADDED BURDEN ON THE SCIENTIFIC-TECHNICAL COMMUNITY, TO ADOPT A COMMON LANGUAGE UNDERSTANDABLE TO BOTH. IT WAS MY EXPERIENCE THAT MANY OF THE SOLICITORS IN THE OCCUPATIONAL SAFETY AND HEALTH AGENCY WERE VERY WELL VERSED IN SCIENTIFIC AND TECHNICAL MATTERS. INDEED, ON SOME SUBJECTS SOME WERE BETTER VERSED THAN THEIR TECHNICAL COUNTERPARTS IN THE AGENCY. THE SCIENTIST OR ENGINEER, IN TURN, WAS VERY FAMILIAR WITH THE LEGAL PROCEDURES NECESSARY UNDER THE STATUTE AND WAS OFTEN CALLED UPON TO APPEAR IN VARIOUS CONTESTS AND HEARINGS INVOLVING THE AGENCY. FOR THE TECHNOLOGIST-SCIENTIST, THE OVER-LAY OF FAMILIARITY WITH THE ROLE OF THE COURTS AND THE LEGAL PROFESSION IN THESE REGULATIONS IS A NECESSITY.

ON THE OTHER HAND, THERE ARE THOSE WHO BELIEVE THAT THE LEGAL PROFESSION IS TOO DEEPLY INVOLVED IN THESE MATTERS. CERTAINLY THE ENTRY OF THE LEGAL PROFESSION INTO THESE FIELDS HAS CAUSED SOME CUMBERSOME PROCEDURES WHICH INEVITABLY LEAD TO DELAY, BUT LET US NOT FORGET THAT THIS HAS ALSO CLARIFIED MANY ISSUES AND HAS, IN NO UNCERTAIN TERMS, INDICATED THE SERIOUS INTENT OF THE REGULATORY

AGENCIES TO BRING ABOUT SOCIETAL CHANGES IN THESE FIELDS. AND MOST IMPORTANT, DUE PROCESS OF LAW HAS BEEN ASSURED TO ALL INVOLVED.

WITH REGARD TO THIS, PERHAPS THE MOST IMPORTANT ROLE OF THE SCIENTIFIC-TECHNICAL-BUSINESS COMMUNITIES, THE PROVISION OF DATA AND PRESENTATION OF TESTIMONY, SOME WORDS OF JOHN GARDNER IN HIS BOOK, NO EASY VICTORIES, ARE PARTICULARLY PERTINENT.

"WE HAVE ALL SEEN MEN WITH LOTS OF BRIGHT IDEAS BUT NO PATIENCE WITH THE MACHINERY BY WHICH IDEAS ARE TRANSLATED INTO ACTION. AS A RULE, THE MACHINERY DEFEATS THEM. IT IS A PITY, BECAUSE THE PROFESSIONAL AND ACADEMIC MAN CAN PLAY A USEFUL ROLE IN PRACTICAL AFFAIRS. BUT TOO OFTEN HE IS A DILETTANTE. HE DIPS IN HERE OR THERE; HE GIVES BITS OF ADVICE ON A DOZEN FRONTS; HE NEVER GETS HIS HANDS DIRTY WORKING WITH ONE PIECE OF THE SOCIAL MACHINERY UNTIL HE KNOWS IT WELL. HE WILL NOT TAKE THE TIME TO UNDERSTAND THE SOCIAL INSTITUTIONS AND PROCESSES BY WHICH CHANGE IS ACCOMPLISHED."

AND AGAIN:

"THE CURSE OF THE CITIZEN ACTION IS THE GLANCING BLOW-- A LITTLE WORK ON THIS COMMITTEE AND ON TO THE NEXT ONE; A LITTLE WORK ON THAT COMMITTEE AND ON TO SOMETHING ELSE... NEVER GETTING FAR ENOUGH BELOW THE SURFACE TO UNDERSTAND

HOW THE MACHINERY WORKS IN WHATEVER ACTIVITY HE IS TRYING TO CHANGE; JUST LINGERING LONG ENOUGH TO SIGN THE COMMITTEE REPORT, NOT STAYING LONG ENOUGH TO SEE WHAT THE CONSEQUENCES OF THE REPORT ARE."

THERE ARE OTHER MAJOR PROVISIONS OF REGULATIONS WHICH SHOULD AFFECT BEHAVIOR OF RESPONSIBLE MANAGERS. THUS, THERE ARE NOT ONLY CIVIL PENALTIES IN THE OSHA AND THE TOXIC SUBSTANCES CONTROL ACT, THERE ARE CRIMINAL PENALTIES, INCLUDING JAIL SENTENCING WHERE WILLFUL VIOLATIONS CAN BE DEMONSTRATED. MANY STATUTES ALSO HAVE PROVISIONS FOR CITIZEN SUITS AGAINST THOSE ADMINISTERING THE ACTS AT THE FEDERAL LEVEL.

HOW SHOULD THE MEDICAL PROFESSION RESPOND TO THESE EXTENSIVE REQUIREMENTS OF FEDERAL LEGISLATION? FIRST, YOU SHOULD RECOGNIZE, BECAUSE THOSE IN GOVERNMENT ARE COMING TO RECOGNIZE, THAT THE PRIVATE SECTOR KNOWS MORE ABOUT ITS AFFAIRS THAN MEMBERS OF THE GOVERNMENT WILL EVER KNOW. FEDERAL REGULATORY EFFORT IS DEPENDENT ON THE KNOWLEDGE CONTRIBUTED BY THE REGULATEE. YOU KNOW MORE ABOUT FEASIBLE MEDICAL PRACTICES IN THE INDUSTRY YOU ARE INVOLVED WITH THAN OSHA KNOWS. THOSE IN OSHA ARE TRYING TO MEET THEIR RESPONSIBILITIES UNDER THE ACT AND THEY WILL DO THE BEST THEY CAN. HOW DO

YOU WISH TO BE REGULATED? THE ONLY HOPE FOR FEASIBLE REGULATIONS IS FOR VOLUNTEERING OF INFORMATION ON YOUR PART. IN GENERAL, YOU GET THE TYPE OF REGULATION YOU HELP TO SHAPE

AS YOU MAY KNOW, OSHA STANDARDS REQUIREMENTS INCLUDE RECORD-KEEPING, MONITORING, SPECIFIC ENGINEERING CONTROLS AND A HOST OF WORK PRACTICES, INCLUDING PROTECTIVE CLOTHING AND EQUIPMENT, JOB ROTATION IN REGULATED AREAS, HYGIENIC FACILITIES, LABELLING, AND MEDICAL SURVEILLANCE. TRAINING AND EDUCATION REQUIREMENTS ARE ALSO USUALLY INCLUDED. LARGE NUMBERS OF SPECIFIC STANDARDS DEALING WITH INDIVIDUAL CHEMICALS ARE PROJECTED FOR THE FUTURE. THERE IS ALSO A DEVELOPMENTAL EFFORT DIRECTED AT GENERIC STANDARDS, STANDARDS THAT CUT ACROSS INDIVIDUAL COMPOUNDS. THE MOST RECENT ILLUSTRATION OF THIS APPROACH IS THE GENERIC STANDARD ENTITLED "IDENTIFICATION, CLASSIFICATION AND REGULATION OF CARCINOGENS". UNDER THE TOXIC SUBSTANCES CONTROL ACT THE PRIVATE SECTOR WILL BE REQUIRED TO PROVIDE INFORMATION ON THE INDIVIDUAL CHEMICALS USED BY EACH FIRM. THE GOVERNMENT WILL REQUIRE THE "CHEMICAL IDENTITY, PRODUCTION LEVELS, USES, BY-PRODUCTS, ANY HEALTH AND SAFETY STUDIES, ALLEGED ADVERSE

REACTIONS, AND OTHER FACTORS OF ENVIRONMENTAL SIGNIFICANCE." ALL TESTING OF NEW PRODUCTS WILL BE PERFORMED BY THE PRIVATE SECTOR WITH INFORMATION PROVIDED TO THE GOVERNMENT.

THE MEDICAL REQUIREMENTS UNDER OSHA STANDARDS DIFFER FOR MANY SUBSTANCES REGULATED. I HAVE BROUGHT ALONG A SUMMARY DOCUMENT BY MR. FURR, OF WESTINGHOUSE CORPORATION IN PITTSBURGH, WHICH INDICATES ALL CURRENT REQUIREMENTS UNDER THE STANDARDS. IT SHOULD BE NOTED THAT THIS ADMINISTRATION HAS CONTINUED THE STRESS ON HEALTH ASPECTS OF OSHA CONCERNS RATHER THAN SAFETY ASPECTS. DR. EULA BINGHAM HAS COMMITTED HERSELF TO CONTINUING THE INCREASED ATTENTION TO HEALTH HAZARDS IN THE WORK ENVIRONMENT BY INCREASING THE NUMBER OF HYGIENISTS IN THE AGENCY AND THE NUMBER OF HEALTH STANDARDS PROMULGATED. MOST RECENTLY, DR. BINGHAM HAS INDICATED THAT STANDARDS FOR COTTON DUST, BERYLLIUM, BENZENE, ARSENIC, NICKEL AND LEAD WILL BE PROMULGATED BY THE END OF 1977. BECAUSE OF THE REQUIREMENTS OF THE STANDARDS AND THE THIRD PARTY LIABILITY POSSIBILITIES, IT IS NECESSARY TO SET UP A MAJOR DATA KEEPING FACILITY IN EACH COMPANY. IT WILL BE NECESSARY IN THE FUTURE TO HAVE READILY AVAILABLE RECORDS

OF PERSONNEL EXPOSURE TO CHEMICALS. IT WOULD BE A MISTAKE AT THIS TIME TO THINK THAT THE "HEAT IS GOING TO DECREASE". IT IS NOT. THE HEAT IN THIS FIELD IS GOING TO INCREASE; THERE ARE CERTAIN IMMEDIATE STEPS THAT THE PRIVATE SECTOR AND THE MEDICAL PROFESSION CAN TAKE TO ENSURE THAT REGULATORY ACTIVITY IN THE FUTURE IS WELL BASED. I WOULD LIKE TO REVIEW THESE.

1. THERE MUST BE CORPORATE COORDINATE AND PROFESSIONAL MANPOWER IN THIS FIELD. DURING MY TENURE AT OSHA I ADDRESSED THE PRESIDENTS AND VICE-PRESIDENTS OF THE PETROLEUM REFINING ASSOCIATION, APPROXIMATELY 200 MEN AND WOMEN. I ASKED HOW MANY HAD EVER MET OR TAKEN PART IN THE HIRING OF THE INDUSTRIAL HYGIENIST OR SAFETY PROFESSIONAL IN THEIR FIRM. APPROXIMATELY THREE HANDS WERE RAISED. I THEN ASKED HOW MANY ~~HAD~~ MET OR TAKEN PART IN THE HIRING OF THEIR CHIEF DESIGNER. VIRTUALLY EVERY HAND IN THE AUDIENCE WENT UP. THE AUDIENCE DID NOT REALIZE THAT THE HEALTH AND SAFETY PERSONNEL IN THEIR ORGANIZATION IS A CRITICAL MEMBER OF THE COMPANY AND THAT THEIR FUTURE LIABILITY IS VERY MUCH DEPENDENT ON THE EFFORTS OF THAT INDIVIDUAL. THE PRIVATE SECTOR MUST PLAN FOR

TESTING FACILITIES OR MUST MAKE INSTITUTIONAL ARRANGEMENTS FOR UTILIZATION OF THE TESTING FACILITIES OF OTHERS FOR CHEMICALS. HOPEFULLY, THIS WILL BE DONE ON AN ASSOCIATION WIDE BASIS SO THAT AN INDIVIDUAL FIRM IS NOT RESPONSIBLE FOR THE TOTAL COST BURDEN. DO YOU, AS PHYSICIANS, KNOW THE CHEMICALS THAT ARE USED IN THE FACILITIES THAT YOU ARE EXAMINING MEN TO WORK IN? DO YOU KNOW THE POTENTIAL OF THESE CHEMICALS FOR CAUSING HARM? MANY OF THEM ARE MARKETING UNDER TRADE NAMES. ARE YOU AWARE OF THEIR INGREDIENTS?

2. BECAUSE OF THE ABOVE QUESTIONS, EACH FIRM MUST REVIEW ITS PROCEDURES IN HANDLING, LABELLING, MONITORING, SURVEILLANCE, ETC., OF THE CHEMICALS IN ITS INVENTORY. IT MUST JUDGE THE ADEQUACY OF CURRENT PROCEDURES AND MOVE TO IMPROVE PROCEDURES WHERE THEY ARE INADEQUATE. IF PERSONNEL ARE NOT IN HOUSE TO DO THIS, THEN SUCH SKILLED PERSONNEL MUST BE HIRED FROM FIRMS PROVIDING THIS SERVICE. YOU, AS THE PHYSICIANS CHARGED WITH THE HEALTH OF THE PEOPLE IN THE INDUSTRY, MUST APPLY THE PRESSURE TO MANAGEMENT TO DO THIS.

3. THE TOXICOLOGICAL DATA IN HAND WITH REGARD TO THE CHEMICALS UTILIZED MUST BE REVIEWED. YOU ARE KEY PERSONS IN THIS REVIEW PROCEDURE.

4. DO YOU HAVE CLOSE TIES OR ASSOCIATIONS WITH YOUR COUNTER-PARTS IN OTHER PLANTS? OR DO YOU OPERATE ALONE? I DO NOT KNOW THE PROCEDURES FOR SHARING OF KNOWLEDGE IN YOUR GROUP, BUT IT IS ESSENTIAL TO ESTABLISH SUCH PROCEDURES.

5. ESTABLISHMENT OF RECORDKEEPING AND DATA STORAGE. I REFER TO THIS ACTIVITY AS "DOCUMENTING THE NEGATIVE". PRIOR TO THE ADVENT OF ALL THIS REGULATION, THE PRIVATE SECTOR USED TO DOCUMENT POSITIVE CASES--CASES WHERE PEOPLE WERE HURT. TODAY IT IS NECESSARY TO DOCUMENT THE NEGATIVE, TO INDICATE IN YOUR RECORDS THAT YOUR FACILITIES DID, INDEED, ADHERE TO ALL CURRENT STANDARDS AND REGULATIONS. IF PERSONS ARE INJURED IN THE FUTURE AND THEY HAVE AT ONE TIME OR ANOTHER BEEN EXPOSED TO POTENTIALLY HAZARDOUS CONDITIONS IN YOUR FACILITY, THERE IS A HIGH PROBABILITY THAT THEY WILL ATTEMPT TO RELATE THEIR MEDICAL CONDITION TO THAT EXPOSURE. ONLY BY DOCUMENTING THE NEGATIVE CAN YOU AVOID THE ASSOCIATED LIABILITY.

6. EDUCATION OF MANAGEMENT PERSONNEL IS CRUCIAL. THIS EDUCATIONAL PROCESS MUST INCLUDE THE TECHNICAL EXPERT, AS WELL AS

SENIOR MANAGEMENT PERSONNEL. MANY FIRST LINE MANAGERS ARE UNAWARE OF THE RAMIFICATIONS OF THE REGULATIONS FOR THEIR JOBS AND THEIR COMPANIES. THEY ARE STILL LIVING EXCLUSIVELY IN THE WORLD OF PRODUCTION LINE CHECKPOINTS AT CERTAIN HOURS OF THE DAY, CHECKS OF VOLUME PRODUCTION, QUALITY CONTROL OF PRODUCTS, ETC. THEY HAVE NOT BUILT INTO THEIR AUTOMATIC REFLEXES THE HEALTH AND SAFETY ASPECTS OF THE ENVIRONMENT, ASPECTS AS IMPORTANT AS THE FORMER PRODUCTION CONCERNS. HEALTH AND SAFETY MUST BE MADE A LINE MANAGEMENT RESPONSIBILITY. IT IS A WAY OF DOING BUSINESS THAT IS WHAT THE REGULATORY EFFORT IS ALL ABOUT.

7. REVIEW OF MEDICAL SURVEILLANCE PROCEDURES. IT IS NECESSARY FOR MANAGEMENT TO APPRISE ITSELF OF THE ADEQUACY OF MEDICAL SURVEILLANCE PROCEDURES. THESE PROCEDURES ARE NOT ABSTRUSE AND DIFFICULT TO COMPREHEND. ARE YOU, AS PHYSICIANS, EXPLOITING THE MYSTIQUE OF MEDICINE? IF SO, IT IS INAPPROPRIATE. MOST SENIOR MANAGEMENT PERSONNEL ARE FULLY CAPABLE OF UNDERSTANDING MEDICAL TERMINOLOGY AND THE TESTS THAT SHOULD BE PERFORMED AND THE RESULTS OBTAINED THEREFROM. IT IS THE OBLIGATION OF MEDICAL SPECIALISTS

TO MAKE THEIR WORK UNDERSTANDABLE TO THE MANAGER. IT IS ONLY TOO COMMON TO HAVE SENIOR MANAGEMENT PERSONNEL ASSIGN ALL RESPONSIBILITY TO THE PHYSICIAN AND NOT EVEN QUERY THE PHYSICIAN ON PROCEDURES AND RESULTS. WE COULD FURTHER DISCUSS SPECIFIC CASES OF HOW THIS HAS CAUSED MAJOR PROBLEMS TO BUSINESS MANAGERS.

FINALLY, ARE YOU, AS AN OCCUPATIONAL PHYSICIAN, THINKING PREVENTIVE MEDICINE? OR ARE YOU IN YOUR PART-TIME RESPONSIBILITIES IN AN INDUSTRIAL FACILITY PRACTICING CURATIVE OR HEROIC MEDICINE? OUR MEDICAL SCHOOLS ARE STILL ORIENTED TOWARDS CURATIVE MEDICINE, BUT OCCUPATIONAL HEALTH IS A BRANCH OF PREVENTIVE MEDICINE. YOU ARE PERHAPS THE MOST IMPORTANT PERSON IN THE OCCUPATIONAL HEALTH AND SAFETY TEAM TO GIVE WEIGHT TO PREVENTIVE MEASURES IN THE FACILITY. ARE YOU STILL IN THE MINDS OF THOSE IN THE PLANT, THE "DOC" THAT WILL ASSIST THEM WHEN THEY GET HURT? IF THEY THINK OF YOU THAT WAY, YOU ARE NOT FULFILLING THE ROLE OF AN OCCUPATIONAL HEALTH PHYSICIAN. UNFORTUNATELY, THE PROFESSION OF OCCUPATIONAL MEDICINE IS UNDER A CLOUD. A RECENT CODE OF ETHICS WAS ADOPTED BY THE AMERICAN ASSOCIATION OF OCCUPATIONAL MEDICINE. THERE ARE CHARGES OF

THE ALLEGIANCE OF PHYSICIANS TO THEIR COMPANIES AND NOT TO THEIR CLIENTS, THE WORKERS. ALL OF THESE CONFLICTS FACE YOU AS YOU PURSUE YOUR PROFESSIONAL ROLE. I CANNOT OVERSTRESS THE IMPORTANCE OF THAT ROLE NOR THE NEED FOR YOU TO EXAMINE IN DEPTH THE WAY IN WHICH YOU ARE RISING TO THE DEMANDS OF THE AMERICAN WORK-PLACE--DEMANDS REFLECTED IN THE REGULATIONS WE HAVE DISCUSSED.